IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

JUDITH CAMPBELL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.**
	)	
C. R. BARD, INC., a New Jersey corporation,	)	
	)	
and	)	
	)	
BECTON DICKINSON, INC., a New Jersey corporation,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	
	)	

COMPLAINT

Plaintiff JUDITH CAMPBELL ("Plaintiff"), by and through her counsel, brings this Complaint to set forth against Defendants C.R. BARD, INC. and BECTON DICKINSON, INC. (collectively, "Bard" or "Defendants," as the context may require) for injuries suffered as a result of the implantation of defective pelvic mesh products designed, manufactured and marketed by Defendants. In support, Plaintiff states and avers as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiff Judith Campbell is a resident and citizen of Holly, Oakland County, Michigan.

2. Defendant C. R. Bard, Inc. ("Bard") is a New Jersey corporation and a wholly owned subsidiary of Defendant Becton Dickinson, Inc., which also is a New Jersey corporation. The principal place of business of both Defendants is 1 Becton Drive, Franklin Lakes, NJ 07417-1880. Upon information and belief, Defendant Becton Dickinson has succeeded to the liabilities

of Defendant Bard.

3. All acts and omissions of Defendants C.R. Bard and Becton Dickinson (collectively "Defendants"), as described herein, were done by their agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

4. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs.

5. Defendants have significant contacts with this federal judicial district such that they are subject to the personal jurisdiction of this District Court.

6. A substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this federal judicial district, including Plaintiff's implant surgery, the sale of Bard's Alyte product that was implanted in Plaintiff, certain of Plaintiff's injuries suffered as a result of the defective Bard Alyte pelvic mesh product, and Plaintiff's explant surgery. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

FACTUAL BACKGROUND

7. Bard designed, manufactured, packaged, labeled, marketed, sold, and distributed the Bard Alyte polypropylene pelvic mesh product implanted in Plaintiff on September 6, 2014. Dr. Dionysios Veronikis performed surgery to implant the product at Mercy Hospital, St. Louis, St. Louis County, Missouri.

8. Plaintiff suffered injuries as a result of the defective nature of the Bard Alyte pelvic mesh product. The numerous inherent defects of the Bard Alyte pelvic mesh product are more

fully described below. Plaintiff's injuries include, but are not limited to, chronic pelvic pain, vaginal pain, dyspareunia, and other injuries.

9. On January 10, 2015, as a result of her injuries caused by the defective and unreasonably dangerous Bard Alyte pelvic mesh product, Plaintiff underwent surgery to excise her Bard Alyte product and otherwise treat the injuries and disfigurement caused by the Bard Alyte pelvic mesh product. Dr. Dionysios Veronikis performed this surgery at Mercy Hospital in St. Louis, Missouri.

10. Bard's Alyte pelvic mesh product contains monofilament polypropylene mesh.

11. On November 20, 2009, Bard submitted to the Food and Drug Administration its 510(k) premarket notice of intent to market the Bard Alyte polypropylene pelvic mesh product. Bard sought and obtained FDA clearance to market the product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the product.

12. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Bard Alyte pelvic mesh product and Bard's other pelvic mesh products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

13. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional

disabilities.

14. Following a significant increase in the number of reported adverse events associated with the use of surgical mesh for transvaginal repair, the FDA has taken several, escalating actions regarding these products.

15. The polypropylene mesh utilized in the Bard Alyte pelvic mesh product implanted in Plaintiff is substantially similar to the mesh material utilized in other Bard polypropylene pelvic mesh products.

16. In July 2011, the FDA issued a Safety Communication, wherein it identified concerns of "serious complications associated with surgical mesh for transvaginal repair of POP" and issued new recommendations about the use of surgical mesh for transvaginal repair of POP.

17. In September 2011, the FDA convened a public meeting of the Obstetrics and Gynecology Devices Panel to discuss the benefits and risks of this use and, subsequently, issued 131 orders to conduct postmarket surveillance studies to 34 manufacturers of surgical mesh for transvaginal repair of POP, including Bard.

18. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

19. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk

individuals in whom the benefit of mesh placement may justify the risk."

20. In January 2016, the FDA reclassified surgical mesh for transvaginal repair of POP into the highest risk class of devices (class III), which requires premarket approval (PMA) applications rather than Section 510(k) clearance.

21. In April 2019, the FDA ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of POP to stop selling and distributing their products in the U.S. immediately. The FDA advised women who have had transvaginal mesh placed for the surgical repair of POP to "continue with their annual and other routine check-ups and follow-up care" and to "notify their health care professionals if they have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex. They should also let their health care professional know if they have surgical mesh, especially if they plan to have another surgery or other medical procedures. Women who were planning to have mesh placed transvaginally for the repair of POP should discuss other treatment options with their doctors."

22. Defendants knew or should have known about the risks and complications of surgical mesh used for the pelvic repair of POP at the time Plaintiff was implanted with Bard Alyte.

23. Defendants knew or should have known that its polypropylene pelvic mesh products, including the Bard Alyte (collectively, where appropriate, "the Products") unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

24. The scientific evidence shows that the material from which Defendants' pelvic mesh products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including

Plaintiff.

25. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

26. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Bard Alyte pelvic mesh product was unreasonably susceptible to degradation and fragmentation inside the body.

27. The Bard Alyte pelvic mesh product was unreasonably susceptible to shrinkage and contraction inside the body.

28. The Bard Alyte pelvic mesh product was unreasonably susceptible to "creep," or gradual elongation and deformation when subjected to prolonged tension inside the body.

29. The Bard Alyte pelvic mesh product was unreasonably susceptible to causing immune reactions that result from the use of polypropylene, causing adverse reactions and injuries;

30. The Bard pelvic mesh products, including the Bard Alyte, were marketed to the medical community and to patients as safe, effective, and reliable medical devices implanted by safe, effective, and minimally invasive surgical techniques and as safer and more effective when compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence and other competing products.

31. The Bard Alyte pelvic mesh product was unreasonably omitted the risks, dangers, defects, and disadvantages of its pelvic mesh products, including the Bard Alyte, and advertised, promoted, marketed, sold and distributed the Bard Alyte pelvic mesh product as a safe medical

device when Bard knew or should have known that the Bard Alyte pelvic mesh product, like its other pelvic mesh products, was not safe for its intended purposes, and that the Bard Alyte pelvic mesh product would cause, and did cause, serious medical problems and, in some patients, including Plaintiff, catastrophic injuries.

32. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Bard Alyte pelvic mesh product has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating corrective operations, such as that required by Plaintiff herein, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making it defective under the law.

33. The specific nature of the Bard Alyte pelvic mesh product's defects includes, but is not limited to, the following:

a. the use of polypropylene in the Bard Alyte pelvic mesh product and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Bard Alyte pelvic mesh product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh, causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Bard Alyte pelvic mesh product, including, but not limited to, the propensity of the product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the propensity of the product for "creep," or gradually to elongate and deform when subject to prolonged tension inside the body;

e. the inelasticity of the product, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction and results in continuing injury over time; and

g. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer's instructions.

34. The Bard Alyte product is also defective due to Bard's failure adequately to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the use of polypropylene in the Bard Alyte pelvic mesh product and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the product's propensities to contract, retract, and/or shrink inside the body;

c. the product's propensities for degradation, fragmentation and/or creep;

d. the product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

e. the rate and manner of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the product;

g. the risk of chronic infections resulting from the product;

h. the risk of permanent pelvic scarring as a result of the product;

i. the risk of recurrent, intractable pelvic pain and other pain resulting from the product;

j. the need for corrective or revision surgery to adjust or remove the product;

k. the severity of complications that could arise as a result of implantation of the product;

l. the hazards associated with the product;

m. the product's defects described herein;

n. treatment of pelvic organ prolapse with the product is no more effective than feasible available alternatives;

o. treatment of pelvic organ prolapse with the product exposes patients to greater risk than feasible available alternatives;

p. treatment of pelvic organ prolapse with the product makes future surgical repair more difficult than feasible available alternatives;

q. use of the product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. complete removal of the product may not be possible and may not result in complete resolution of the complications, including pain.

35. Defendants have underreported information about the propensity of the Bard Alyte

to fail and cause injury and complications and has made unfounded representations regarding the efficacy and safety of the Bard Alyte through various means and media.

36. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Bard Alyte.

37. Defendants failed to design and establish a safe, effective procedure for removal of the Bard Alyte, or to determine if a safe, effective procedure for removal of the product exists.

38. Feasible and suitable alternatives to the Bard Alyte have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

39. The Bard Alyte pelvic mesh product was at all times utilized and implanted in a manner foreseeable to Bard, as Bard generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

40. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Bard Alyte pelvic mesh product and the aftercare of patients implanted with the product.

41. The Bard Alyte implanted in Plaintiff was in the same or substantially similar condition as it was when it left Bard's possession, and in the condition directed by and expected by Bard.

42. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Bard Alyte and other Bard pelvic mesh products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

43. In many cases, women, including Plaintiff, have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

44. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

45. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

46. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

47. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the Bard Alyte implanted in Plaintiff.

48. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products, including the Bard Alyte implanted in Plaintiff.

49. The Bard Alyte as designed, manufactured, distributed, sold and/or supplied by Defendants was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Bard's knowledge of lack of safety.

50. As a result of having the Bard Alyte implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

51. All preceding paragraphs are hereby incorporated by reference as if fully set forth herein.

52. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Bard Alyte.

53. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Bard Alyte. Defendants breached their aforementioned duty by:

a. Failing to design the Bard Alyte so as to avoid an unreasonable risk of harm to women in whom the Bard Alyte pelvic mesh product was implanted, including Plaintiff;

b. Failing to manufacture the Bard Alyte so as to avoid an unreasonable risk of harm to women in whom the Bard Alyte pelvic mesh product was implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Bard Alyte so as to avoid an unreasonable risk of harm to women in whom the Bard Alyte pelvic mesh product was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Bard Alyte so as to avoid an unreasonable risk of harm to women in whom the Bard Alyte pelvic mesh product was implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Bard Alyte.

54. The reasons that Defendants' negligence caused the Bard Alyte to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Bard Alyte causes an immune reaction that results from such material, causing adverse reactions and injuries;

b. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Bard Alyte to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

c. the propensity of the Bard Alyte for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

d. the inelasticity of the Bard Alyte, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation, walking); and

e. the propensity of the Bard Alyte for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

f. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer's instructions.

55. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Bard Alyte's propensities to contract, retract, and/or shrink inside the body;

b. the Bard Alyte's propensities for degradation, fragmentation and/or creep;

c. the Bard Alyte's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Bard Alyte;

f. the risk of chronic infections resulting from the Bard Alyte;

g. the risk of permanent vaginal or pelvic scarring as a result of the Bard Alyte;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Bard Alyte;

i. the need for corrective or revision surgery to remove the Bard Alyte;

j. the severity of complications that could arise as a result of implantation of the Bard Alyte;

k. the hazards associated with the Bard Alyte;

l. the Bard Alyte's defects described herein;

m. treatment of pelvic organ prolapse with the products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse with the Bard Alyte makes future surgical repair more difficult than feasible available alternatives;

p. use of the Bard Alyte puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Bard Alyte due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Bard Alyte may not be possible and may not result in complete resolution of the complications, including pain.

s. the risk of immune reaction that results from the use of polypropylene material in the Bard Alyte, causing adverse reactions and injuries;

56. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

57. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

58. The Bard Alyte implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to their design. As previously stated, the Bard Alyte's design defects include, but are not limited to:

a. the use of polypropylene material in the Bard Alyte causes an immune reaction that results from such material, causing adverse reactions and injuries;

b. biomechanical issues with the design of the Bard Alyte, including, but not limited to, the propensity of the Bard Alyte to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the propensity of the Bard Alyte for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

e. the inelasticity of the Bard Alyte, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation, walking);

f. the propensity of the Bard Alyte for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

g. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer's instructions.

h. the risk of immune reaction that results from the use of polypropylene material in the Bard Alyte, causing adverse reactions and injuries;

59. As a direct and proximate result of the Bard Alyte's aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

60. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

61. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

62. The Bard Alyte implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff.

63. As a direct and proximate result of the Bard Alyte's aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

64. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing,

labeling, packaging and selling a defective product.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

65. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

66. The Bard Alyte implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Bard did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Bard Alyte's propensities to contract, retract, and/or shrink inside the body;

b. the Bard Alyte's propensities for degradation, fragmentation, disintegration and/or creep;

c. the Bard Alyte's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Bard Alyte;

f. the risk of chronic infections resulting from the Bard Alyte;

g. the risk of permanent vaginal or pelvic scarring as a result of the Bard Alyte;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Bard Alyte;

i. the need for corrective or revision surgery to remove the Bard Alyte

j. the severity of complications that could arise as a result of implantation of the Bard Alyte;

k. the hazards associated with the Bard Alyte;

l. the Bard Alyte's defects described herein;

m. treatment of pelvic organ prolapse with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse with the Bard Alyte exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse with the Bard Alyte makes future surgical repair more difficult than feasible available alternatives;

p. use of the Bard Alyte puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Bard Alyte due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Bard Alyte may not be possible and may not result in complete resolution of the complications, including pain.

s. the risk of immune reaction that results from the use of polypropylene material in the Bard Alyte, causing adverse reactions and injuries;

67. As a direct and proximate result of the Bard Alyte's aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not

limited to, obligations for medical services and expenses, and/or lost income, and other damages.

68. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT V: BREACH OF EXPRESS WARRANTY

69. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

70. Bard made assurances as described herein to the general public, hospitals and health care professionals that the Bard Alyte pelvic mesh product was safe and reasonably fit for its intended purposes.

71. Plaintiff and/or her healthcare provider chose the Bard Alyte based upon Bard‘s warranties and representations as described herein regarding the safety and fitness of the Bard Alyte.

72. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that Bard Alyte pelvic mesh product was safe, merchantable, and reasonably fit for its intended purposes.

73. Defendants breached these express warranties because the Bard Alyte implanted in Plaintiff was unreasonably dangerous and defective as described herein and not as Defendants had represented.

74. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiff, placing Plaintiff’s health

and safety in jeopardy.

75. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT VI: BREACH OF IMPLIED WARRANTY

76. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

77. Defendants impliedly warranted that the Bard Alyte pelvic mesh product was merchantable and was fit for the ordinary purposes for which they were intended.

78. When the Bard Alyte pelvic mesh product was implanted in Plaintiff to treat her pelvic organ prolapse, the Bard Alyte pelvic mesh product was being used for the ordinary purposes for which it was intended.

79. Plaintiff, individually and/or by and through her physician, relied upon Bard’s implied warranties of merchantability in consenting to have the Bard Alyte implanted in her.

80. Defendants breached these implied warranties of merchantability because the Bard Alyte implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted.

81. Defendants' breach of their implied warranties resulted in the implantation of

unreasonably dangerous and defective products in the body of Plaintiff, placing said Plaintiff's health and safety in jeopardy.

82. As a direct and proximate result of Defendants breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

COUNT VIII: PUNITIVE DAMAGES

83. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

84. Defendants sold their Products to the healthcare providers of the Plaintiff and other healthcare providers in Missouri and throughout the United States without doing adequate testing to ensure that the Bard Alyte pelvic mesh product was reasonably safe for implantation in the female pelvic area.

85. Defendants sold the Products to Plaintiff's health care providers and other health care providers in Missouri and throughout the United States in spite of their knowledge that the Bard Alyte and other Bard products can shrink, disintegrate and/or degrade inside the body and cause the other problems set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other women.

86. Defendants ignored reports from patients and health care providers throughout the

United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Products as safe and effective.

87. Defendants knew their pelvic mesh products, including the Bard Alyte pelvic mesh product, were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

88. Defendants withheld material information from the medical community and the public in general, including Plaintiff, regarding the safety and efficacy of the Products.

89. Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

90. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by Bard's pelvic mesh products.

91. Notwithstanding the foregoing, Defendants continue to aggressively market Bard's pelvic mesh products to consumers, without disclosing the true risks associated with the Products.

92. Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

93. Defendants continue to conceal and/or fail to disclose to the public, including Plaintiff, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

94. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL CLAIMS.

CAREY, DANIS & LOWE

/s/Jeffrey J. Lowe

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